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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MITRA, RITA	

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 08/11/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/028,248	MALAYANKAR ET AL.	
	Examiner	Art Unit	
	Rita Mitra	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *42-53 and 60-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *42-53 and 60-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/02, 5/03, 8/03*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

Applicants' election without traverse of Group II (claims 5-14, 30, 33) in response to Office Action dated April 20, 2004, filed on May, 20, 2004 is acknowledged. Claims 1-41 and 54-59 have been canceled. New claims 60-64 have been added and entered. Therefore, claims 42-53 and 60-64 are currently pending and are under examination.

Information Disclosure Statement

The information disclosure statement filed on May 30, 2001 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP 609 because the copies of the references listed in PTO Form 1449 are not submitted. Therefore the information referred to therein has not been considered as to the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title"

Claims 42-53 and 60-64 are rejected under 35 U.S.C. 101 because the specification does not provide either a specific or substantial asserted utility or a well-established utility, and thus, does not support the claimed invention. The claimed nucleic acids are not supported by either a specific asserted utility or a well established utility because the specification fails to assert any utility for the claimed nucleic acids or the encoded proteins and neither the specification as filed nor any art of record disclose or suggest any activity for the claimed nucleic acids or the encoded proteins such that another non-asserted utility would be well established. Note, because the claimed invention is not supported by a specific asserted utility for the reasons set forth above, credibility cannot be assessed. The reasons are as follows:

The specification, on pages 6-8, Table A describes protein designated as NOV1, set forth in SEQ ID NO: 211 encoded by the nucleic acid sequence of SEQ ID NO: 210

(NOV1c, Table A) to which the instant invention relates. The NOV1c is a variant of NOV1, which includes the 3260 of nucleotide sequence of SEQ ID NO: 210 (page 24+, Table 1E) that encodes a polypeptide having amino acid sequence of SEQ ID NO: 211 (page 25+, Table 1F). The specification further indicates at page 8 that the NOV1 is homologous to the Stabilin family of proteins, thus the NOV1 nucleic acids, polypeptides, antibodies and related compounds will be useful in therapeutic and diagnostic application, which is associated with various diseases and disorders. Examples of many diseases have been listed (page 8, 37 and 223-226) but the specification does not indicate explicitly the correlation of the role of any composition comprising NOV1 to a specific disease treatment or prevention. Also, a homology to the Stabilin family of proteins does not conclude that NOV1 polynucleotide encoding NOV1 polypeptide would be useful in therapeutic application for the treatment or prevention of cancer, angeogenesis, inflammation, CNS disorders, metabolic disorders and other pathologies/disorders (see page 8, lines 8-12). The specification further indicates at page 26 the variants of NOV1c (see Table 1G, page 26), derived from a domain (Fascilin domain) between residues 85-636. However, the specification fails to provide any function of these variants containing a Fascilin domain or the function of the full length NOV1c from where the variants are derived from.

General uses of polynucleotides set forth in the specification, as filed include use to express encoded polypeptides, to screen a human cDNA or genomic library, to use as educational tools, genetic analysis, diagnostic applications, to use as probes and primers (pages 154-159), use for antisense nucleic acids (pages 165-167), therapeutic application (pages 223-226), screening and detection methods (pages 201-208) chromosomal mapping (pages 208-210), tissue typing (pages 210-211). These general uses are not specific and substantial, as they do not require any one particular sequence. For example, for the asserted utility of genetic analysis such as chromosomal mapping, the chromosomal location has not been assigned to nucleotide sequence of SEQ ID NO: 210. Therefore, one of ordinary skill in the art would have to perform additional tests to determine which specific chromosomal location is identified by the polynucleotide sequence of SEQ ID NO: 210, the complements and the fragments thereof, and further

determine whether the particular sequence would be practical to use in chromosomal mapping studies. There is no other particular identifying information associated with the claimed nucleic acid molecule of the invention.

Based on the specification (pages 6-8, 24-26), any biological activity of the nucleic acid and encoded polypeptide itself has not been provided. However, generalized statements regarding uses have been provided on pages 154-159, 201-208 and 223-226 of the specification, but are discussed in the context of being used for further research, but to do what? The function/biological activity of the protein is not per se set forth in the instant specification. One skilled in the art should not have to engage in discovering genomics to learn how to use the invention. This situation requires carrying out future additional research to identify or reasonably confirm a "real world" context of use and therefore do not define specific and substantial utility.

Claim 42 drawn to a nucleic acid molecule comprising SEQ ID NO: 210 except that the nucleotide at position 887 is a nucleotide other than thymine (T) or the nucleotide at position 1144 is a nucleotide other than adenosine (A); wherein the nucleotide at position 887 is other than thymine (claim 43); wherein the nucleotide at position 887 is cytosine (claim 44). Claim 45 drawn to a nucleic acid molecule comprising SEQ ID NO: 210 except that the nucleotide at position 1034 is a nucleotide other than cytosine (C) or the nucleotide at position 1244 is a nucleotide other than thymine (T); wherein the nucleotide at position 1034 is other than cytosine (claim 46); wherein the nucleotide at position 1034 is cytosine (claim 47). Claim 48 drawn to a nucleic acid molecule comprising SEQ ID NO: 210 except that the nucleotide at position 1223 is a nucleotide other than cytosine (C) or the nucleotide at position 1416 is a nucleotide other than adenine (A) or the nucleotide at position 1629 is other than thymine (T); wherein the nucleotide at position 1223 is other than cytosine (claim 49); wherein the nucleotide at position 1223 is thymine (claim 50). Claim 51 drawn to a nucleic acid molecule comprising SEQ ID NO: 210 except that the nucleotide at position 832 is a nucleotide other than adenine (A) or the nucleotide at position 2003 is a nucleotide other than thymine (T); wherein the nucleotide at position 832 is other than adenine (claim 52); wherein the nucleotide at position 832 is guanine(claim 53). However, the specification

does not describe the functional properties of the polynucleotides of claims 42-53, and the structural information is limited. While the specification enumerates several known assays for biological activity (pages 201-208), it does not guide the selection of a specific assay that would be used to screen the biological activities of the claimed polynucleotides and polypeptides. Examples of many therapeutic methods have been described in pages 223-226 but the specification does not indicate explicitly the correlation of the role of the claimed polynucleotides and encoded polypeptides to a specific disease treatment. Moreover, specification fails to provide any information regarding molecules having Stablin family activity.

Claims 60, 61 and 62 are drawn to a vector/expression vector comprising the nucleic acid of SEQ ID NO: 210, wherein the vector is introduced into host cells to express the protein (claim 62). Although a general description that includes host cells bacteria, yeast, fungal, insect vand mammalian cell have been provided (189-194), specification fails to provide specific recombinant host cells comprising the claimed vectors that demonstrate expression of nucleic acid of SEQ ID NO: 210 of NOV1c clone.

Claims 63 and 64 drawn to a pharmaceutical composition comprising the nucleic acid sequence of claim 42, wherein the composition is contained in a kit (claim 64). The specification on pages 197-201 describes the compositions and kits containing the compositions but does not indicate the function of the nucleic acids and/or the expressed proteins therein. When the function of the nucleic acid or the encoded polypeptide is not known how one skilled in the art would know how to use the invention.

As discussed above, based on the specification it is unclear what activity the claimed nucleic acid molecule and polypeptides encoded therein possess and therefore unclear how a person having skill in the art would be using the claimed polynucleotides and polypeptides.

In the instant case, the failure of applicants to specifically identify why the claimed invention is believed to be useful renders the claimed invention deficient under 35 USC 101. No specific biological activity has been identified for the nucleic acid of SEQ ID NO: 210 and the encoded protein set forth in SEQ ID NO: 211 other than the fact that the protein may be a member of the Stablin family (page 8). The person having

ordinary skill in the art would not be able to identify any specific activity for the protein comprising or related to SEQ ID NO: 211 based on its structure alone for the reasons set forth above. General statements that a composition has an unspecified biological activity or that do not explain why a composition with that activity is believed to be useful fails to set forth a "specific utility." Brenner v. Manson, 383 US 519, 148 USPQ 689 (Sup. Ct.1966) (general assertion of similarities to known compounds known to be useful without sufficient corresponding explanation why claimed compounds are believed to be similarly useful is insufficient under 35 USC 101).

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 42-53 and 60-64 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial or well established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention so that it would operate as intended without undue experimentation.

Claims 42-53 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 42-53 are directed to polynucleotide variants of the sequence of SEQ ID NO: 210. As discussed above, based on the specification (pages 6-8, 24-26) it is unclear what activity the claimed variants possess, what activity the encoded proteins possess and therefore unclear how a person having skill in the art would have used the claimed variants. The specification does not describe the functional properties of these variants, and the structural information is limited.

Conclusion

No claims are allowed.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (571) 272-0954. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Jon Weber, can be reached at (571) 272-0925. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette,1096 OG 30 (November 15, 1989). The Fax Center number is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-0547.

Rita Mitra, Ph.D.
August 3, 2004

Jon P. Weber, Ph.D.
Primary Examiner